REMARKS

Claims 21-25 and 27 are pending in the present application. Claims 21-25 and 27 are rejected. Claims 22, 24, and 25 are amended. Applicant believes that no new matter is added by the foregoing amendments amendment.

Applicant notes that previous rejections of Claim 26 are withdrawn in view of the previous cancellation of this claim. Also withdrawn is the rejection of Claims 22-25 under 35 U.S.C. 112, second paragraph In view of the Applicant's previously filed amendment.

I. Rejections of Claims 21-25 under 35 U.S.C. §101.

The Examiner has maintained the rejection of Claims 21-25 under 35 U.S.C. §101, on the basis of a lack of support by either a credible, specific, and substantial utility, or a well established utility.

The Examiner's rejection is maintained based upon the following reasons:

1) The increase in DCRS9 expression in a helminth challenge does not provide sufficient biological significance;

2) Expression of DCRS9 is not indicative of involvement in innate immunity;

3) The post filing data of the involvement of the ligand for DCRS9 in neutrophil increase in lung is not relevant; and

4) Modulation of innate immunity is not a substantial, specific, and credible utility.

The Examiner is respectfully reminded that there is no requirement to present evidence sufficient to establish that an asserted utility is true "beyond a reasonable doubt" or "as a matter of statistical certainty" (see, M.P.E.P. 2107.02 (VII)). An applicant is only required to provide evidence, if, when considered as a whole, leads the skilled artisan to concluded that the asserted utility is more likely than not true (see, M.P.E.P. 2107.03 (II), emphasis added).

With regard to the Examiner's assertion that DCRS9 expression data does not provide sufficient biological significance, Applicant respectfully disagrees. Using the above standard as the burden of proof, Applicant submits Gygi, et al. (1999) Mol. Cell.

Biol. 19:1720-1730.(Exhibit A) supports the traditional belief that mRNA expression is correlative with protein expression. After examining the expression of over 100 genes, the authors conclude that there is "a general trend of increased protein levels resulting from increased mRNA levels." (see Haynes, page 1726). In fact the correlation coefficient for this general trend was 0.935 (see, Haynes, figure 5). Therefore the correlation between mRNA levels and protein expression is readily apparent.

As noted in Applicant's previous response, expression of DCRS9 increases in helminth challenged mouse lung. Further, the previously submitted declaration of Daniel M. Gorman as well as the Hurst et al. (2002) J. Immunol. 169:443-453 reference both permit the skilled artisan to believe that DCRS9, the receptor for IL-17C, is involved in airway neutrophilia. A ligand normally will not have activity unless it binds to a receptor followed by signaling of the receptor. Taken together, the correlation between expression and protein expression, the higher expression of DCRS9, the discovery of its ligand IL-17C, the involvement of IL-17C in respiratory infiltrate of neutorphils, would lead the skilled artisan to believe that DCRS9 is more likely than not to be biologically significant in airway disorders.

The Examiner's next contention that expression of DCRS9 is not indicative of involvement in innate immunity is incorrect. Again, using the standard for the Applicant's burden of proof noted above, Applicant's submit that the immune cells infiltrating a helminth challenged lung have been shown to be predominantly eosinophils (see, Coffman, et al. (1989) Science 245:308-310; Exhibit B). Eosinophils have long been categorized as cells involved in cellular innate immunity (see, Benjamini and Leskowitz (eds) (1988) Immunology: A Short Course, Alan R. Liss, Inc., New York, NY, pp. 15-16; Exhibit C). Taken this knowledge with the expression data above, one skilled in the art would more likely than not believe that DCRS9 is involved in innate immunity.

The Examiner next asserts that the post filing reference indicating that IL-17C is the ligand for DCRS9 and is involved in increased airway neutrophilia is irrelevant. Specifically the Examiner alleges that the specification does not disclose any possible

ligand for DCRS9 nor that DCRS9 could be an IL-17 family member. Applicant disagrees. The specification clearly demonstrates Applicant's belief that DCRS9 is a receptor in the IL-17 family. The Examiner is directed to page 40, of the specification, where an alignment of DCRS9 and various IL-17R from different species are compared. It is evident that Applicant, at the time of filing, did believe and disclose that DCRS9 was an IL-17 receptor family member. Thus, one skilled in the art would more likely than not believe that DCRS9, through binding of its ligand, would be relevant for increased airway neutrophilia.

In view of the above, one skilled in the art would more likely than not believe that DCRS9 would have substantial, credible, and specific utility, at the very least as a marker for an innate immune response. Thus the binding composition would also have this utility as well.

Applicant submits that the rejection of Claims 21-25 under 35 U.S.C. 101 is overcome by the above arguments. Withdrawal of this rejection is respectfully requested.

II. Rejection of Claims 21-25 and 27 under 35 U.S.C. 112, First Paragraph

The Examiner maintained the rejection of Claims 21-25 and newly rejected Claim 27 under 35 U.S.C. 112, first paragraph for reasons previously set forth. In view of the above, the skilled artisan would clearly know how to make and use the present invention. In view of the foregoing, Applicants believe that this rejection is overcome and its withdrawal is respectfully requested.

III. Rejection of Claims 22 and 24 under 35 U.S.C. 112, Second Paragraph

The Examiner maintained the rejection of Claims 22 and 24 under 35 U.S.C. 112, second paragraph. Claim 22, as amended, defines the binding composition as recommended by the Examiner. As amended, Claim 24 no longer recites ". . . as a source of . . . ". In view of the above amendment, Applicant believes that the rejection

of Claims 22 and 24 under 35 U.S.C. 112, second paragraph is overcome. Withdrawal of this rejection is respectfully requested.

Conclusion

Applicant's current response is believed to be a complete reply to all the outstanding issues of the latest Final Office Action. Further, the present response is a bona fide effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicant respectfully requests reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

Dated: May 21, 2004

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Enclosed:
1. Gygi, et al. (1999) Mol. Cell. Biol. 19:1720-1730; Exhibit A
2. Coffman, et al. (1989) Science 245:308-310; Exhibit B
3. Benjamini and Leskowitz (eds) (1988) Immunology: A Short Course, Alan R. Liss Inc., New York, NY, pp. 15-16; Exhibit C